

IBUPROFEN- ibuprofen capsule, liquid filled
PuraCap Pharmaceutical LLC

Ibuprofen Capsules (Liquid Filled), 200 mg

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)** (present as the free acid and potassium salt)

**nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
 - the common cold
 - muscular aches
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, and white ink

Questions or comments ?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

20 Liquid Filled Capsules

NDC 51013-103-15

NDC 51013-103-15

Ibuprofen

Solubilized Ibuprofen Capsules, 200 mg
Liquid Filled Softgels
Pain Reliever/
Fever Reducer (NSAID)

20 SOFTGELS¹
Liquid Filled Capsules

PuraVation.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Uses ■ temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. ■ temporarily reduces fever

Warnings

- **Ask your doctor before use** if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
- This product may cause a **severe allergic reaction**, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.
- **Do not use** this product if you have ever had an allergic reaction to any pain reliever/fever reducer.
- **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding.

Drug Facts (continued under label)

Distributed by: PuraCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854

Made in China
IBU01-01

Lot No.:
Exp Date:

PEEL HERE

The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed.

■ **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule, 2 capsules may be used ■ do not exceed 6 capsules in 24 hours, unless directed by a doctor ■ children under 12 years: ask a doctor

Each capsule contains: potassium 20 mg

Questions or comments?

call toll free: 1-855-215-8180

Drug Facts (continued)

- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk, if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - leg swelling
 - weakness in one part or side of body
 - slurred speech
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.**

Directions

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink.

Questions or comments? Call toll free: 1-855-215-8180

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Liqui-Gels®

NDC 51013-103-39

Compare to the active ingredient of Advil® Liqui-Gels®*

Ibuprofen

Solubilized Ibuprofen Capsules, 200 mg
Liquid Filled Softgels
Pain Reliever/
Fever Reducer (NSAID)

120
SOFTGELS†
Liquid Filled Capsules

PurvaVation.

Do Not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Drug Facts	Purpose Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)** <small>(present as the free acid and potassium salt)</small> ** nonsteroidal anti-inflammatory drug	Uses temporarily relieves minor aches and pains due to: headache backache menstrual cramps the common cold muscular aches pain of arthritis temporarily reduces fever	Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives facial swelling asthma (wheezing) shock skin redness rash blisters Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older have had stomach ulcers or bleeding problems take a blood thinner (anticoagulant) or steroid drug take other drugs, combination prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.
Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery			
Ask a doctor before use if: stomach bleeding warning applies to you you have problems or serious side effects from taking pain relievers or fever reducers			

Drug Facts (continued under label)

Distributed By: PurvaCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854
Made in China
IBU13-01

Lot No.:
Exp Date:

3 51013-10339 5

**PER
HERE**

PRINCIPAL DISPLAY PANEL

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

120 Liquid Filled Capsules

NDC 51013-103-63

NDC 51013-103-63

Ibuprofen

**Ibuprofen Capsules,
200 mg**
Liquid Filled Softgels
Pain Reliever/
Fever Reducer (NSAID)

10 SOFTGELS*
Liquid Filled Capsules

PuraVation.

READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with
"SEALED for YOUR PROTECTION" is broken or missing.

Uses ■ temporarily relieves minor aches and pains
due to: headache, muscular aches, menstrual
cramps, the common cold, backache, toothache,
minor pain of arthritis. ■ temporarily reduces fever

Warnings

■ Ask your doctor before use if you are pregnant,
under a doctor's care for a serious condition, age 60 or
over, taking any other drug or have stomach problems.
■ This product may cause a **severe allergic reaction**,
especially in people allergic to aspirin. Symptoms
may include: hives, facial swelling, asthma (wheezing),
shock, skin reddening, rash, blisters. If an allergic
reaction occurs, stop use and seek medical help
right away.

■ Do not use this product if you have ever had an allergic
reaction to any pain reliever/fever reducer.

■ **Stomach bleeding warning:** This product contains
a nonsteroidal anti-inflammatory drug (NSAID), which
may cause severe stomach bleeding.

Drug Facts (continued under label)

Distributed by: PuraCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854

Made in China
IBU20-00

Lot No.:

Exp Date:

PEEL
HERE

The chance is higher if you ■ are age 60 or
older ■ have had stomach ulcers or
bleeding problems ■ take a blood
thinning (anticoagulant) or steroid drug
■ take other drugs containing prescription
or nonprescription NSAIDs [aspirin,
ibuprofen, naproxen, or others] ■ have
3 or more alcoholic drinks every day
while using this product ■ take more
or for a longer time than directed.

■ **Heart attack and stroke warning:** NSAIDs,
except aspirin, increase the risk of heart
attack, heart failure, and stroke. These can
be fatal. The risk is higher if you use more
than directed or for longer than directed.

Directions ■ do not take more
than directed ■ the smallest effective
dose should be used ■ adults and
children 12 years and over: take 1 capsule
every 4 to 6 hours while symptoms persist
■ if pain or fever does not respond to 1
capsule, 2 capsules may be used ■ do
not exceed 6 capsules in 24 hours,
unless directed by a doctor ■ children
under 12 years: ask a doctor

Each capsule contains: potassium 20 mg

Questions or comments?

call toll free: 1-855-215-8180

*This product is not manufactured or distributed by Paracap Consumer Healthcare, owner of the registered trademark Advil® Liqui-Gels®.

Distributed By: Paracap Pharmaceutical LLC
20 Kingsbridge Road, Parsippany, NJ 08854
Made in China

Do Not Use if imprinted safety seal under cap is broken or missing.



READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts	Purpose
<p>Active ingredient (in each capsule) Sulbitalol (ibuprofen) equal to 200 mg ibuprofen (NSAID)** (present as the free acid and potassium salt) **nonsteroidal anti-inflammatory drug</p>	<p>Pain reliever/ Fever reducer</p>
<p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ toothache ■ backache ■ menstrual cramps ■ the common cold ■ muscular aches ■ minor pain of arthritis ■ temporarily reduces fever 	
<p>Warnings</p> <p>Allergic alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin redness ■ rash ■ blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older</p>	

NDC 51013-103-63 Compare to the active ingredient of Advil® Liqui-Gels®*

Ibuprofen

Ibuprofen Capsules, 200 mg
Liquid Filled Softgels
Pain Reliever/Fever Reducer (NSAID)

10 SOFTGELS[†] †Liquid Filled Capsules



Drug Facts (continued)

- read all warnings and directions before use. Keep carton.
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients
FD&C green #3, gelatin, medium-chain triglycerides, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution and white ink

Questions or comments? Call toll free: 1-855-215-8180

Drug Facts (continued)

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■ you are taking a diuretic

Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ taking any other drug

When using this product ■ take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint ■ vomit blood ■ have bloody or black stools
 - have stomach pain that does not get better

Drug Facts (continued)

- you have symptoms of heart problems or stroke:
 - chest pain ■ trouble breathing ■ leg swelling
 - weakness in one part or side of body ■ slurred speech
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: potassium 20 mg

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	18mm
Flavor		Imprint Code	PC16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-103-15	1 in 1 CARTON	10/12/2016	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:510 13-103-25	1 in 1 CARTON	10/12/2016	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:510 13-103-26	1 in 1 CARTON	10/12/2016	
3		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:510 13-103-39	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2016	
5	NDC:510 13-103-28	1 in 1 CARTON	10/12/2016	

5		160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:51013-103-29	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2016	
7	NDC:51013-103-38	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2016	
8	NDC:51013-103-31	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/12/2016	
9	NDC:51013-103-22	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2017	
10	NDC:51013-103-41	400 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2017	
11	NDC:51013-103-42	800 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2017	
12	NDC:51013-103-63	1 in 1 CARTON	08/17/2017	
12		10 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206568	10/12/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-103) , analysis(51013-103)

Revised: 12/2019

PuraCap Pharmaceutical LLC